

Fr. Rick

Publications related to ACCORD E4

Design, method and method validation:

• **Acceptability guidelines/approaches**

- Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 1: Cigarette design, testing approach, and review of results, Food Chem. Toxicol. 40(1): 77-91 (2002)
- Carchman, R., Identification of 'animal or organism-based' short-term tests which are available for the assessment of the potentially harmful properties of tobacco smoke, Report of Canada's Expert Committee on Cigarette Toxicity Reduction: Appendix: Invited Papers, p41 (1998)

PROTOTYPE

- Patskan, G.; Hsu, F. Meisgen, T.; Stabbert, R.; Vanscheeuwijck, P.; Veltel, D., Toxicological characterization of a novel cigarette paper, Toxicol. Sci. 54(1): 398 (2000)

• **Harm reduction guidelines/approaches**

Poser (INTOX, CORESTA) - Patskan

• **Identification of targets for harm reduction**

- Haussmann, H.-J.; Rustemeier, K.; Elves, R.G., The use of risk analysis in selecting cigarette smoke constituents for reduction, 2001 Society for Risk Analysis Annual Meeting, Seattle, USA, 02-Dec-2001; 05-Dec-2001 *Manuscript*

• **Smoke chemistry, mainstream constituents**

- Rustemeier, K.; Stabbert, R.; Haussmann, H.-J.; Roemer, E.; Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 2: Chemical composition of mainstream smoke; Food Chem. Toxicol. 40(1): 93-104 (2002)
- Stabbert, R.; Schaefer, K.-H.; Biefel, C.; Rustemeier, K., Analysis of aromatic amines in cigarette smoke, Tobacco Science Research Conference, Greensboro, North Carolina, USA, 09-Sep-2001; 12-Sep-2001
- **PROTOTYPE**
- Diekmann, J.; Biefel, C.; Stabbert, R.; Rustemeier, K., Analysis of unsymdimethylhydrazine in cigarette smoke, Tobacco Science Research Conference, Greensboro, North Carolina, USA, 09-Sep-2001; 12-Sep-2001
- Demetriou, D.; Schepers, G., Determination of benzo(a)pyrene (B(a)P) in complex matrix by multi-dimensional high-performance liquid chromatography, 53rd Tobacco Science Research Conference, C-Montreal, 12-Sep-1999; 15-Sep-1999
- Rustemeier, K.; Plade, J.-J., Determination of nicotine in mainstream smoke, In: Gorrod, J.W.; Jacob, P. (Eds.): Analytical determination of nicotine and related compounds and their metabolites, Amsterdam: Elsevier Science; Chapter 12, pp. 489-529 (1999)

• **Smoke chemistry, sidestream constituents**

• **Smoke chemistry, ETS constituents**

- Gerstenberg, B.; Stinn, W.; Reininghaus, W., Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette, Toxicol. Sci. 60(1): 431 (2001)
- **ACCORD**
- Gerstenberg, B.; Stinn, W.; Reininghaus, W., Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette, Tobacco Science Research Conference, USA-Nashville, 24-Sep-2000; 27-Sep-2000
- **ACCORD**

*Manuscript
(Gerstenberg + Stinn)*

PM3006531162

- **CO biomarker(s)**
 - Vanscheeuwijck, P.; Teredesai, A.; Terpstra, P.M.; Verbeeck, J.; Kuhl, P.; Gerstenberg, B.; Gebel, S.; Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 4: Subchronic inhalation toxicity, Food Chem. Toxicol. 40(1): 113-131 (2002)
- **1,3-Butadiene biomarker(s)**
- **Other biomarkers**
 - Roethig, H.J.; von Holt, K.; Kuhl, P.; McKinney, W.; Zhang, M.; Walk, R.-A., Biomarkers of potential harm in smokers, Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001
 - Kinser, R.D.; Oey, J., Examples of systemic validation for biomarkers of cigarette smoke exposure, Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001
 - Kinser, R.D.; Carchman, R.A.; Leyden, D.E.; Sanders, E.B.; Stabbert, R.; Tricker, A.R.; von Holt, K.; Walk, R.-A., Selection of biomarkers of exposure for a population study of U.S. adult smokers to cigarette smoke, Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001
 - Kinser, R.D.; Carchman, R.A.; Leyden, D.E.; Sanders, E.B.; Stabbert, R.; Tricker, A.R.; von Holt, K.; Walk, R.-A., Selection of biomarkers of exposure for a population study of U.S. adult smokers to cigarette smoke, Toxicology 164: P1A2, 41 (2001)
- **Nicotine biomarkers**
 - Vanscheeuwijck, P.; Teredesai, A.; Terpstra, P.M.; Verbeeck, J.; Kuhl, P.; Gerstenberg, B.; Gebel, S.; Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 4: Subchronic inhalation toxicity, Food Chem. Toxicol. 40(1): 113-131 (2002)
 - Demetriou, D.; Schepers, G., Determination of nicotine and its metabolites in urine by HPLC after DETBA derivatization, Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001
 - Schepers, G.; Demetriou, D.; Stabbert, R.; Diehl, B.; Seeman, J.L., 5'-Hydroxycotinine-N-oxide, a new nicotine metabolite isolated from rat urine, Xenobiotica 29 (8): 793-801 (1999)
 - Gorrod, J.W.; Schepers, G., Biotransformation of nicotine and related compounds, In: Gorrod, J.W.; Jacob, P. (Eds.): Analytical determination of nicotine and related compounds and their metabolites, Amsterdam: Elsevier Science, Chapter 3, pp. 45-67, 1999
 - Schepers, G.; Demetriou, D.; Stabbert, R.; Diehl, B., Isolation and identification of nicotine phase 2 metabolites from smoker's urine, Second Annual Conference, the Society for Research on Nicotine and Tobacco, USA-Washington, 15-Mar-1996; 17-Mar-1996
- **Cytotoxicity**
 - Roemer, E.; Tewes, F.J.; Meisgen, T.J.; Veltel, D.J.; Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 3: In vitro genotoxicity and cytotoxicity, Food Chem. Toxicol. 40(1): 105-111 (2002)

manuscript:
Pilot study;
variability, close

manuscript for
cytotox. claim basis

- **Genotoxicity**

- Schramke, H.; Tewes, F.J.; Roemer, E., Using the mouse lymphoma TK assay to compare the mutagenicity of mainstream smoke condensate from research cigarettes, 41th Annual Meeting of the Society of Toxicology, March 17-21, 2002, Nashville, USA
- Vanscheeuwijck, P.; van Miert, E.; Meurrens, K.; Terpstra, P.M., The micronucleus assay for the determination of cigarette mainstream smoke activity in bone marrow and peripheral blood of rats, *Toxicol. Sci.* 60(1): 431 (2001)
- Roemer, E.; Tewes, F.J.; Meisgen, T.J.; Veltel, D.J.; Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 3: In vitro genotoxicity and cytotoxicity, *Food Chem. Toxicol.* 40(1): 105-111 (2002)
- Tewes, F.J.; Meisgen, T.J.; Gomm, W.A.; Roemer, E.; Carchman, R.A., Cigarette parameters that influence the mutagenicity of mainstream smoke condensate, *Toxicol. Sci.* 48 (1-S) (1999)
- Roemer, E.; Meisgen, T.J.; Tewes, F.J.; Solana, R.P., Discrimination of cigarette mainstream smoke condensates with the Salmonella reverse mutation assay, *Toxicol. Sci.* 42(1-S): 295 (1998)

- **90-Day rat inhalation**

- Vanscheeuwijck, P.; Teredesai, A.; Terpstra, P.M.; Verbeeck, J.; Kuhl, P.; Gerstenberg, B.; Gebel, S.; Carmines, E.L., Evaluation of the potential effects of ingredients added to cigarettes. Part 4: Subchronic inhalation toxicity, *Food Chem. Toxicol.* 40(1): 113-131 (2002)
- Kaegler, M.; Anskeit, E.; Teredesai, A.; Vanscheeuwijck, P.; Terpstra, P., Suitability of different exposure regimens in subchronic inhalation studies with cigarette smoke, *Toxicol. Sci.* 60(1): 431 (2001)
- Kaegler, M.; Teredesai, A.; Vanscheeuwijck, P.; Terpstra, P.; Gerstenberg, B., Comparison of two exposure regimens in rat subchronic inhalation studies with cigarette smoke, *Toxicol. Sci.* 54(1): 17 (2000)
- Roemer, E.; Teredesai, A.; Terpstra, P.; Vanscheeuwijck, P.M.; Haussmann, H.-J., The discriminative power of rat inhalation studies investigating the irritative property of inhalants, *Validity of Animal Models of Human Respiratory Diseases*, USA-Santa Fe, 30-Sep-1998; 2-Oct-1998

- **Smoking topography**

- Walk, R.-A.; Carter, W.H.; Carchman, R.A.; Gear, J.C.; Gomm, W.; Gennings, C.; Kinser, R.D.; Leyden, D.E.; Nelson, B.L.; Tricker, A.R.; von Holt, K., Design for a population study of exposure of U.S. adult smokers to cigarette smoke, *Toxicology* 164: P1A3, 41 (2001)
- Walk, R.-A.; Carter, W.H.; Carchman, R.A.; Gear, J.C.; Gomm, W.; Gennings, C.; Kinser, R.D.; Leyden, D.E.; Nelson, B.L.; Tricker, A.R.; von Holt, K., Design for a population study of exposure of U.S. adult smokers to cigarette smoke, *Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies*, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001
- Kinser, R.D.; Carchman, R.A.; Leyden, D.E.; Sanders, E.B.; Stabbert, R.; Tricker, A.R.; von Holt, K.; Walk, R.-A., Selection of biomarkers of exposure for a population study of U.S. adult smokers to cigarette smoke, *Toxicology* 164: P1A2, 41
- Kinser, R.D.; Carchman, R.A.; Leyden, D.E.; Sanders, E.B.; Stabbert, R.; Tricker, A.R.; von Holt, K.; Walk, R.-A., Selection of biomarkers of exposure for a population study of U.S. adult smokers to cigarette smoke, *Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies*, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001

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- Kinser, R.D.; Oey, J., Examples of systemic validation for biomarkers of cigarette smoke exposure, biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, USA, 25-Oct-2001; 26-Oct-2001
- **Questionnaires for human exposure/risk evaluation**
- **Short-term confined clinical design**
- **Medium-term clinical design** *Technical: SRT or SOT paths?*
- **Surveillance plan** *Poster*

Publ. manuscript

Data¹:

- **Smoke chemistry, mainstream constituents**
 - Voncken, P.; Gerstenberg, B.; Rustemeier, K.; Stabbert, R.; Patskan, G.; Haussmann, H.-J., Chemical analysis of selected cigarette mainstream smoke constituents for comparative product integrity testing, 1998 Tobacco Science Research Conference, USA-Atlanta, 13-Sep-1998; 16-Sep-1998
PROTOTYPE
 - Terpstra, P.M.; Reininghaus, W.; Solana, R.P., Safety evaluation of an electrically heated cigarette, Toxicol. Sci. 42(1-S): 295 (1998)
PROTOTYPE
 - Terpstra, P.M.; Reininghaus, W., Chemical and biological evaluation of smoke from an electrically heated cigarette, 2nd Congress of Asian Society of Toxicology ASIATOX II, K-Cheju, 23-Aug-00; 25-Aug-00
PROTOTYPE
 - Rustemeier, K.; Patskan, G.; Haussmann, H.-J., The influence of a modified puffing regimen on the yields of smoke constituents from electrically heated and conventional research cigarettes, The Toxicologist 54(1): 16 (2000)
PROTOTYPE
 - Stabbert, R.; Schaefer, K.-H.; Biefel, C.; Rustemeier, K., Analysis of aromatic amines in cigarette smoke, Tobacco Science Research Conference, Greensboro, North Carolina, USA, 09-Sep-2001; 12-Sep-2001
PROTOTYPE
 - Stabbert, R.; Voncken, P.; Rustemeier, K.; Haussmann, H.-J.; Roemer, E.; Schaffernicht, H.; Patskan, G., Toxicological evaluation of an electrically heated cigarette. Part 2: Chemical composition of mainstream smoke (to be re-submitted)
PROTOTYPE
 - Roemer, E.; Vanscheeuwijck, P.; Elves, R.G.; Fournier, J., Ammonium magnesium phosphate in the paper wrapper of an electrically heated cigarette reduces the biological activity of the resulting smoke, 41th Annual Meeting of the Society of Toxicology, USA-Nashville, 17-Mar-2002; 21-Mar-2002
PROTOTYPE
- **Smoke chemistry, ETS constituents**
 - Gerstenberg, B.; Stinn, W.; Reininghaus, W., Comparison of environmental tobacco smoke from an electrically heated and a conventional

¹ Prototype (P) or market product (M)

cigarette, Toxicol. Sci. 60(1): 431 (2001)

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- Gerstenberg, B.; Stinn, W.; Reininghaus, W., Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette, Tobacco Science Research Conference, USA-Nashville, 24-Sep-2000; 27-Sep-2000

ACCORD

- Lau and Hirnickel, J. Exp. Anal. Envir. Epidemiol.

Main synth (Lau + Gerstenberg)

Richard: Title

- **Cytotoxicity**

- Terpstra, P.M.; Reininghaus, W.; Solana, R.P., Safety evaluation of an electrically heated cigarette, Toxicol. Sci. 42(1-S): 295 (1998)

PROTOTYPE

- Terpstra, P.M.; Reininghaus, W., Chemical and biological evaluation of smoke from an electrically heated cigarette, 2nd Congress of Asian Society of Toxicology ASIATOX II, K-Cheju, 23-Aug-00; 25-Aug-00

PROTOTYPE

- Tewes, F.J.; Meisgen, T.J.; Veltel, D.J.; Roemer, E.; Patskan, G., Toxicological evaluation of an electrically heated cigarette. Toxicological evaluation of an electrically heated cigarette. Part 3: Genotoxicity and cytotoxicity of mainstream smoke (to be re-submitted)

PROTOTYPE

- Tewes, F.J.; Veltel, D.J.; Heil, M.; Solana, R.P., Discrimination of cigarette mainstream smoke with the Neutral Red Uptake cytotoxicity assay, Toxicol. Sci. 42(1-S): 295 (1998)

PROTOTYPE

- Roemer, E.; Vanscheeuwijck, P.; Elves, R.G.; Fournier, J., Ammonium magnesium phosphate in the paper wrapper of an electrically heated cigarette reduces the biological activity of the resulting smoke, 41th Annual Meeting of the Society of Toxicology, USA-Nashville, 17-Mar-2002; 21-Mar-2002

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- Terpstra, P.M.; Reininghaus, W.; Solana, R.P., Safety evaluation of an electrically heated cigarette, Toxicol. Sci. 42(1-S): 295 (1998)

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- Roemer, E.; Meisgen, T.J.; Tewes, F.J.; Solana, R.P., Discrimination of cigarette mainstream smoke condensates with the Salmonella reverse mutation assay, Toxicol. Sci. 42(1-S): 295 (1998)

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- Roemer, E.; Vanscheeuwijck, P.; Elves, R.G.; Fournier, J., Ammonium magnesium phosphate in the paper wrapper of an electrically heated

cigarette reduces the biological activity of the resulting smoke, 41th
Annual Meeting of the Society of Toxicology, USA-Nashville, 17-Mar-2002;
21-Mar-2002
PROTOTYPE



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- **90-Day rat inhalation**

- Terpstra, P.M.; Reininghaus, W.; Solana, R.P., Safety evaluation of an electrically heated cigarette, Toxicol. Sci. 42(1-S): 295 (1998)
PROTOTYPE
- Vanscheeuwijck, P.M.; Anskelt, E.A.; Teredesai, A.; Solana, R.P., Equi-effect design for subchronic inhalation toxicity studies comparing conventional and novel cigarette prototypes, Toxicol. Sci. 42(1-S): 295 (1998)
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- Terpstra, P.M.; Reininghaus, W., Chemical and biological evaluation of smoke from an electrically heated cigarette, 2nd Congress of Asian Society of Toxicology ASIATOX II, K-Cheju, 23-Aug-00; 25-Aug-00
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- Terpstra, P.M.; Teredesai, A.; Vanscheeuwijck, P.M.; Verbeeck, J.; Schepers, G.; Radtke, F.; Kuhl, P.; Gomm, W.; Anskelt, E.; Patskan, G., Toxicological evaluation of an electrically heated cigarette. Part 4: Subchronic inhalation toxicology (to be re-submitted)
PROTOTYPE
- Roemer, E.; Vanscheeuwijck, P.; Elves, R.G.; Fournier, J., Ammonium magnesium phosphate in the paper wrapper of an electrically heated cigarette reduces the biological activity of the resulting smoke, 41th Annual Meeting of the Society of Toxicology, USA-Nashville, 17-Mar-2002; 21-Mar-2002
PROTOTYPE

- **Smoking topography**

Poster

- **Short-term confined clinical study**

- Am.Coll.Clin. Pharm. Sep. 2002 (poster)
- Roethig et al. (exposure and effects, Sep. 2002)
- NN (Ames, Dec. 2002)

} *design now*

- **Medium-term clinical study**